Randomized comparison of percutaneous Viabahn stent grafts vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral arterial occlusive disease

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Objective: **This randomized prospective study was designed to compare the effectiveness of treating superficial femoral artery occlusive disease percutaneously with expanded polytetrafluoroethylene (ePTFE)/nitinol self-expanding stent grafts vs surgical femoral-to-above knee (AK) popliteal artery bypass with synthetic graft material.**

Methods: **From March 2004 to May 2005, 100 limbs in 86 patients with femoral-popliteal arterial occlusive disease were identified. Patients had symptoms ranging from claudication to rest pain, with or without tissue loss, and were prospectively randomized for treatment into one of two groups. The limbs were treated percutaneously with angioplasty and one or more self-expanding stent grafts (n = 50) or surgically with femoral-to-AK popliteal artery bypass using synthetic Dacron or ePTFE grafts (n = 50). The mean ± SD total length of artery stented was 25.6 ± 15 cm. Follow-up evaluation with ankle-brachial indices and color flow duplex sonography imaging were performed at 3, 6, 9, and 12 months after treatment.**

Results: **Patients were monitored for a median of 18 months. No statistical difference was found in the primary patency ($P = .895$) or secondary patency ($P = .861$) between the two treatment groups. Primary patency at 3, 6, 9, and 12 months of follow-up was 84%, 82%, 75.6%, and 73.5% for the stent graft group and 90%, 81.8%, 79.7%, and 74.2% for the femoral-popliteal surgical group. Thirteen patients in the stent graft group had 14 reinterventions, and 12 reinterventions occurred in the surgical group. This resulted in secondary patency rates of 83.9% for the stent graft group and 83.7% for the surgical group at the 12-month follow-up.**

Conclusions: **Management of femoral-popliteal arterial occlusive disease using percutaneous treatment with a stent graft is comparable with surgical revascularization with conventional femoral-to-AK popliteal artery bypass using synthetic material up to 12 months. Longer-term follow-up would be helpful in determining ongoing efficacy. (J Vasc Surg 2007; 45:10-16.)**

Endovascular therapy has dramatically altered the treatment of peripheral arterial disease. Lesions previously thought amenable only to open surgical bypass can now be successfully managed percutaneously. In an international trial study group, Lammer et al[1] deployed the Hemobahn endoprosthesis (W. L. Gore & Associates, Flagstaff, Ariz) in 80 limbs with occlusive femoral-popliteal lesions. A primary patency of 90% at 6 months and 79% at 12 months was achieved. Subsequent to this report, the graft delivery system was modified (although the graft itself remained without change), and it was renamed the Viabahn endoprosthesis.

Ultimately, percutaneous endovascular treatment of superficial femoral arterial occlusive disease will not be fully embraced until direct comparisons are made with open surgical bypass. Although most consider vein bypass to be the gold standard in surgical treatment of severe atherosclerotic disease, synthetic grafting is often used in current practice for femoral–popliteal above knee (AK) bypass. The purpose of our study was to compare the efficacy of the stent graft vs open surgical femoral–AK popliteal bypass in the treatment of superficial arterial occlusive disease.

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MATERIALS AND METHODS

Study design. The study was a prospective, randomized trial conducted at a single private institution between March 2004 and May 2005. The study was approved by the US Food and Drug Administration (FDA) with an investigational device exemption (IDE) and was approved and monitored by the hospital Institutional Review Board.

During the study period, patients with symptoms of lifestyle-altering claudication or rest pain with or without tissue loss were evaluated for treatment. A clinical examination and non-invasive studies, including the ankle-brachial index (ABI) and color-flow duplex ultrasonography, were used to confirm infrainguinal disease. Patients

Table I. Patient demographics

	*Stent graft group**	*Surgical bypass group**	P
Patients (n)	40	46	
Age, mean ± SD (range)	71.8 ± 9.9 (40-84)	66.9 ± 10.7 (40-86)	.0333†
Smoking history	22	27	.8280‡
Diabetes mellitus	14	20	.5090‡
CAD	13	22	.1886‡
Hypertension	30	42	.0763‡
Hyperlipidemia	23	21	.2862‡
COPD	2	8	.0973‡

CAD, Coronary artery disease; *COPD,* chronic obstructive pulmonary disease.
*Four patients randomized a limb to both treatment groups.
†Two-tailed t-test with pooled variances.
‡Two-tailed Fisher's exact test.

subsequently underwent digital subtraction angiography (DSA) or computed tomography angiography (CTA) to evaluate the location and extent of atherosclerotic disease in the infrainguinal segment.

To be included in the study, patients had to have atherosclerotic stenotic or occlusive lesions of the superficial femoral artery, with no significant aortoiliac disease. In addition, the infrapopliteal segment had to be patent and at least one single vessel run-off to the ankle had to be present. Patients had to be acceptable surgical candidates in the event they were randomized to the surgical arm.

Enrolled patients were prospectively randomized by limb into two treatment groups: percutaneous endovascular treatment with the stent graft, or open surgical femoral–AK popliteal artery bypass with synthetic graft.

Study population. Between March 2004 and May 2005, 100 limbs in 86 patients met the inclusion criteria. Forty patients (50 limbs) were randomized to treatment with the stent graft, and 46 patients (50 limbs) were randomized to treatment with femoral–AK popliteal artery bypass. In four patients undergoing treatment for bilateral disease, one limb was randomized into the stent graft group and one limb was randomized into the surgical bypass group. The demographic data and associated comorbidities are summarized in Table I. Although there was a significant difference in patient age between the two treatment groups, no significant difference was found in the patient comorbidities.

Stent graft design. The stent graft that was used for endovascular treatment was made from a self-expanding helical nitinol stent and a tube of ultra-thin expanded polytetrafluoroethylene (ePTFE). Although the graft was not FDA-approved for use in the superficial femoral artery (SFA) at the outset of this study, current FDA-approved graft sizes for use in the SFA are 6 to 8 mm in diameter and 2.5 to 15 cm in length.

Endovascular technique. All procedures were performed under sterile conditions in an endovascular suite with a fixed imaging unit or in an operating room suite with a C-arm (General Electric OEC 9800, GE Healthcare, Waukesha, Wisc). Percutaneous vascular access was obtained by standard Seldinger technique[2] from either the ipsilateral femoral artery in an antegrade manner or from the contralateral femoral artery. Once access was achieved, a 45-cm-long 8F or 9F sheath was inserted, depending on the diameter of stent graft to be deployed. Systemic heparin (100 U/kg) was then administered to fully anticoagulate the patient.

Standard guidewire techniques were used to cross the atherosclerotic lesion. Occlusions were crossed using a subintimal dissection technique with re-entry into the true lumen. Predilation of the lesion then was performed with a 4 or 5 mm angioplasty balloon. The length of the balloon was selected to dilate only the lesion to be treated and to avoid dilatation of any nonstenotic vessel.

The stent graft was deployed to cover the entire diseased arterial segment. Grafts with diameters of 5 to 7 mm were used, depending on the diameter of the native artery; most were 5 mm. If possible, the graft was deployed so that it landed with the stent margins no more than 1 cm into the segment of normal artery superiorly and inferiorly. Care was taken not to cover large collateral vessels, if feasible, while ensuring coverage of the diseased segment of artery. When multiple stent grafts were used for longer lesions, the devices were overlapped by at least 1 cm.

After deployment, the stent grafts were dilated and modeled with a 5-mm, 6-mm, or 7-mm balloon to correspond with the size of the stent used, and completion angiography was performed. Specific attention was given not to dilate outside the stent graft. Lesion length and length of stented artery segments were measured with calibrated in-plane markers at the time of the initial procedure.

After treatment, patients were started on aspirin (81 to 325 mg/d) and clopidogrel (75 mg/d) therapy for a minimum of 3 months. Patients who were receiving warfarin therapy before treatment for other associated conditions were continued on the drug in addition to aspirin at 81 mg/d. Clopidogrel was not used in these patients.

Open surgical technique. Femoral–AK popliteal artery bypass was accomplished in the usual surgical fashion. After standard surgical exposure of the vessels, each patient was systemically anticoagulated with heparin (100 U/kg) before graft insertion. The choice of conduit was left to the discretion of the operating surgeon and was either ePTFE or Dacron. Graft diameters were 6 to 8 mm; most were 7 mm. Postoperatively, patients were placed on an antiplatelet regimen similar to that described for the stent graft patients.

Postoperative assessment and follow-up examination. After discharge, follow-up at 3, 6, 9, and 12 months included clinical exam, color flow Doppler ultrasound imaging, and determination of the ABI. Color flow Doppler ultrasound imaging was performed at a laboratory approved by the Intersocietal Commission for the Accreditation of Vascular Laboratories and was used to assess patency of grafts and to detect recurrent arterial or graft stenosis. Primary and secondary patency rates

Table II. Pretreatment distribution of chronic limb ischemia Rutherford categories[3]

Clinical grade	*Stent graft limbs (n = 50)*	*Surgical bypass limbs (n = 50)*
0	0	0
1	2	1
2	23	20
3	16	10
4	4	10
5	4	7
6	1	2

Generalized Fisher's exact test, $P = .3676$.

Table III. Lesion TransAtlantic Inter-Society Consensus (TASC) classification per limb

TASC	*Stent graft (n = 50)*	*Surgical bypass (n = 50)*
A	2	1
B	6	8
C	37	31
D	5	10

Generalized Fisher's exact test, $P = .4739$.

and graft failure rates were defined by the criteria described by Rutherford.[3] Graft failure was defined as stent graft or bypass graft thrombosis, restenosis of >50% of the treated arterial segment immediately above or below the stent graft or bypass graft (anastomotic or stent landing zone sites), intrastent or intragraft restenosis >50%, or a decrease in the ABI of ≥0.15.

Statistical analysis. The life-table method was used to calculate primary and secondary patency rates vs time of follow-up. The log-rank test was used to determine the statistical difference between patency rates between the two treatment groups. The Fisher exact test (generalized version for tables beyond 2 × 2) was used to evaluate differences in patient demographics, grades of chronic limb ischemia, and TransAtlantic Inter-Society Consensus (TASC) classification. $P < .05$ was considered statistically significant. Mean data are presented with ± SD or ranges.

RESULTS

Between March 2004 and May 2005, 50 limbs in 40 patients were treated percutaneously with the stent graft, and 50 limbs in 46 patients were treated surgically with femoral–AK popliteal artery bypass.

Pretreatment clinical categories of chronic limb ischemia using Rutherford's classification[3] for the treated limbs are shown in Table II. No significant difference in pretreatment clinical grades between the two treatment groups was noted.

By following the TASC grading system[4] for femoropopliteal lesions, each limb in both treatment groups was assigned a TASC classification as summarized in Table III. The TASC classifications between the two treatment groups were not significantly different.

Stent graft placement was technically successful in 100% of the treated limbs in the stent graft treatment group. A total of 114 devices were implanted in the 50 limbs, with a mean of 2.3 stent grafts placed per limb. The mean diameter of the stent grafts was 5.7 mm (range, 5 to 7 mm). The mean total length of artery covered with the stent graft was 25.6 ± 15 cm.

After treatment, 37 (93%) of 40 patients in the stent graft group took clopidogrel and aspirin for a minimum of 3 months. One patient claimed an allergy to clopidogrel, and two others refused to take it. These three patients did take aspirin, however.

Femoral–AK popliteal artery bypass was successfully performed in 100% of the treated limbs in the surgical treatment group. Dacron grafts were used in 32 limbs (64%), and ePTFE was used in 18 limbs (36%). The mean diameter of the synthetic bypass grafts was 7.4 mm (range, 7 to 8 mm).

In the surgical bypass group, 24 (52%) of 46 patients were on a clopidogrel and aspirin regimen post-treatment. Seventeen patients were taking aspirin only as recommended by the treating surgeon. The remaining five patients were taking warfarin preoperatively and were continued only on this regimen postoperatively.

Immediate procedure-related and early postoperative, nonthrombotic complications were observed in four (8%) of 50 limbs (40 patients) treated with the stent graft. In one patient, a dissection was created in the SFA during passage of a guidewire. The stent graft was used to exclude the dissection along with the atherosclerotic lesion. Another patient experienced transient mild leg edema in the treated limb. Deep venous thrombosis was ruled out, and the edema resolved. One patient reported severe thigh pain in the treated limb that required readmission to the hospital for pain management. The pain resolved ≤24 hours without any identifiable pathology. One final patient had a small groin hematoma that resolved without intervention.

In the surgical bypass group, early postoperative complications were observed in three (6%) of 50 limbs (46 patients). These three patients developed a groin lymphocele, a groin seroma, and a small superficial groin wound dehiscence, respectively. The patient with a groin lymphocele was returned to the operating room for washout and reclosure of the wound. The other two patients were managed nonoperatively.

An improvement in grade of the Rutherford classification occurred in all limbs (100%) in the stent graft treatment group and in 46 limbs (92%) in the surgical bypass group. The overall mean improvement was 2.4 clinical grades in both groups.

Median follow-up duration was 18 months for both treatment groups. Follow-up was available for 31 (78%) of 40 patients in the stent graft group. Four patients died during the study period from conditions unrelated to infrainguinal disease, and all but one of these patients

had tissue loss preoperatively. Five patients were lost to follow-up.

During this period, 13 of the stent grafts failed secondary to thrombosis. An early graft thrombosis occurred in the recovery room the same day of the procedure in one patient. One stent graft thrombosis occurred within the first month after stent graft implantation. The other 11 stent graft thromboses were detected after a mean period of 5.4 ± 3 months after stent graft placement.

Of the 13 grafts that thrombosed, five (38%) were successfully declotted with mechanical balloon thrombectomy and one was successfully recanalized with intra-arterial tissue plasminogen activator–mediated lysis. In six (46%), attempts at thrombectomy or lysis were unsuccessful, and these patients eventually underwent open surgical bypass (five to the AK popliteal artery). Finally, one of the patients with a thrombosed stent graft was found to have heparin-induced thrombocytopenia and amputation eventually was performed owing to progressive tissue loss. This patient had tissue loss preoperatively.

In two of the patients who underwent thrombectomy of their clotted stent grafts, an underlying stenosis was detected after post-thrombectomy angiography. One patient had a high-grade stenosis just distal to the stent graft. The other patient had a proximal stenosis. In both cases, the stenotic area was treated with angioplasty and stent graft placement.

In one patient (two limbs), both lower extremities thrombosed simultaneously. This patient was found to have bilateral lower extremity embolization after new onset atrial fibrillation. Thirty days before occlusion, a routine follow-up arterial duplex demonstrated no stenosis within either limb and the patient had palpable bilateral pedal pulses. One limb was eventually opened with thrombectomy, but the other limb required femoral–below-knee bypass for limb salvage.

Another patient in the stent graft group with a patent graft was found to have a short segment proximal arterial stenosis detected at follow-up color flow duplex sonography imaging, which was confirmed at angiography to be approximately 30% to 40%. This segment was treated with angioplasty alone. Overall, 14 interventions had to be performed in the stent graft treatment group during 12 months.

None of the three patients in the stent graft group that were not taking clopidogrel after treatment had a thrombosed stent graft. Of the 13 thrombosed stent grafts, 11 (84%) were TASC C lesions. Of the other two thrombosed grafts, one (8%) was a TASC A lesion and one (8%) was a TASC D lesion.

Follow-up was available for 37 (80%) of 46 patients in the surgical bypass group. Four patients died owing to conditions unrelated to their infrainguinal disease. Five patients were lost to follow-up.

During this period, 10 incidences of synthetic graft thrombosis occurred, of which seven (70%) were TASC C lesions and three (30%) were TASC D lesions; none were TASC A or B lesions. One occurred within the first month after implantation. The other nine were detected a mean of 6.9 ± 4 months after graft placement. Four of the 10 thrombosed synthetic grafts were successfully declotted with mechanical balloon thrombectomy. Three patients underwent below knee popliteal artery bypass with great saphenous vein conduit after thrombectomy failed.

In three separate instances, ischemia from clotted grafts eventually led to below knee amputation. In two additional cases, progressive tissue loss despite patent grafts led to two additional amputations. All instances of limb amputation occurred in patients that had tissue loss preoperatively.

One patient in the surgical group with a patent graft was found on follow-up duplex ultrasound to have a distal native arterial stenosis. This was confirmed at angiography, and the stenosis was treated with balloon angioplasty and stent placement. As already mentioned, one patient with a groin lymphocele had an operative intervention. Overall, 12 interventions had to be performed in the surgical bypass group during 12 months.

Cumulative primary and secondary patency rates were calculated with use of the life-table method. At follow-up at 3, 6, 9 and 12 months, the respective primary patency rates were 84.0%, 82.0%, 75.6%, and 73.5%, for the stent graft group and 90.0%, 81.8%, 79.7%, and 74.2% for the surgical bypass group (Table IV). Secondary patency at the 12-month follow-up was 83.7% for the stent graft group and 83.9% for the surgical bypass group (Table V). There was no significant difference in primary patency ($P = .895$) or secondary patency ($P = .861$) between the two treatment groups. Limb salvage at the 12-month follow-up was not significantly different at 98.0% for the stent graft patients and 89.6% for surgical bypass patients ($P = .094$) (Table VI). Baseline ABIs were were 0.57 ± 0.19 for the stent graft group and 0.46 ± 0.22 for the surgical bypass group. At 12 months, the mean improvement in ABI was 0.23 for the stent graft treatment group and 0.37 for the surgical bypass group ($P = .113$).

Length of hospital stay was analyzed for both groups. The mean hospital stay was 0.9 ± 0.8 days for the stent graft group was and 3.1 ± 1.8 days for the surgical group. This difference proved to be significant (t test, $P < .001$).

DISCUSSION

Initial attempts to treat SFA atherosclerotic disease percutaneously were made with transluminal angioplasty (PTA).[5] Although effective in short-segment stenosis, PTA has been disappointing as a primary treatment for longer SFA stenosis.[6] Further investigation led to the use of angioplasty, followed by stent placement. The results of these studies were equivocal to PTA patency,[7] most likely due to neointimal hyperplasia.

The patency of percutaneously placed stent grafts for SFA disease was published by Lammer et al in 2000.[1] This multicenter study demonstrated 1-year primary and secondary patency rates of 79% and 93% in 80 limbs. Bauermeister et al[8] treated 35 patients and achieved primary and

Table IV. Primary patency in femoral-popliteal bypass group and stent graft group

Time post-treatment (months)	*N at risk at start of interval*	*N events during interval**	*N censored during interval**	*% Free from loss of patency*	*95% CI*
Operative (day 0-30)					
Fem-pop bypass	50	2 (2)	0 (0)	0.960	(0.849, 0.990)
Stent graft	50	2 (2)	0 (0)	0.960	(0.849, 0.990)
3 months (day 31-136)					
Fen-pop bypass	48	3 (5)	1 (1)	0.900	(0.776, 0.957)
Stent graft	48	6 (8)	1 (1)	0.840	(0.705, 0.917)
6 months (day 137-227)					
Fem-pop bypass	44	4 (9)	2 (3)	0.818	(0.680, 0.901)
Stent graft	41	1 (9)	1 (2)	0.820	(0.682, 0.902)
9 months (day 228-319)					
Fem-pop bypass	38	1 (10)	8 (11)	0.797	(0.655, 0.885)
Stent graft	39	3 (12)	1 (3)	0.756	(0.611, 0.854)
12 months (day 320-456)					
Fem-pop bypass	29	2 (12)	8 (19)	0.742	(0.587, 0.846)
Stent graft	35	1 (13)	7 (10)	0.735	(0.587, 0.837)

CI, Confidence interval.
Log-rank $P = .895$.
*Number in parenthesis represents cumulative events or censored observations through end of interval.

Table V. Secondary patency in femoropopliteal bypass group and stent graft group

Time post-treatment (months)	*N at risk at start of interval*	*N events during interval**	*N censored during interval**	*% Free from loss of patency*	*95% CI*
Operative (day 0-30)					
Fem-pop bypass	50	2 (2)	0 (0)	0.960	(0.849, 0.990)
Stent graft	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
3 months (day 31-136)					
Fem-pop bypass	48	2 (4)	1 (1)	0.920	(0.801, 0.969)
Stent graft	50	6 (6)	1 (1)	0.880	(0.752, 0.944)
6 months (day 137-227)					
Fem-pop bypass	45	3 (7)	2 (3)	0.859	(0.726, 0.930)
Stent graft	43	1 (7)	1 (2)	0.860	(0.728, 0.930)
9 months (day 228-319)					
Fem-pop bypass	40	1 (8)	8 (11)	0.837	(0.701, 0.915)
Stent graft	41	1 (8)	1 (3)	0.839	(0.703, 0.916)
12 months (day 320-456)					
Fem-pop bypass	31	0 (8)	11 (22)	0.837	(0.701, 0.915)
Stent graft	39	0 (8)	9 (12)	0.839	(0.703, 0.916)

CI, Confidence interval.
Log-rank *P* value = .861.
*Number in parenthesis represents cumulative events or censored observations through end of interval.

secondary patency rates of 73.2% and 82.6% at 12 months. In 2003, Jahnke et al[9] reported primary assisted patency rates at 12 and 24 months of 82.4% and 80.3%, and secondary patency was 88.3% and 83.2%.

Our study is the first, to our knowledge, to prospectively randomize patients to percutaneous and surgical arms in treatment of disease in the SFA and then directly compare the outcomes. The prior 11 studies of stent grafts have relied on previously published reports of AK bypass patency and historical data for comparison. Historical controls are useful, but prospective, randomized trials allow direct comparison with the most current therapy.

Our technical success rate of 100% mirrors that of many other published trials. Complications were seen in 8% of the patient limbs in the percutaneously treated group. One patient had to be readmitted to the hospital for severe thigh pain. Saxon et al[10] noted the phenomenon of thigh pain after stent graft placement. The pain is thought to be secondary to overdilation of the SFA and may be avoided by not oversizing more than 10% of the native diameter.[10] Minor complications occurred in two other patients, and the symptoms of both patients resolved with observation alone.

Arterial occlusions in the stent graft group were seen within all TASC classifications. Interestingly, two of these cases showed there were underlying lesions at the proximal and distal end of the stent graft that became evident after removal of the thrombus. They were successfully treated by angioplasty and stenting. Deutschman et al[11] described a similar phenomenon in their series of 17 patients. The

Table VI. Limb salvage in femoropopliteal bypass group and stent graft group

Time post-treatment (months)	*N at risk at start of interval*	*N events during interval**	*N censored during interval**	*% Free from loss of patency*	*95% CI*
Group: femoropopliteal bypass					
Operative (day 0-30)					
Fem-pop bypass	50	2 (2)	0 (0)	0.960	(0.849, 0.990)
Stent graft	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
3 months (day 31-136)					
Fem-pop bypass	48	1 (3)	2 (2)	0.940	(0.825, 0.980)
Stent graft	50	1 (1)	4 (4)	0.980	(0.866, 0.997)
6 months (day 137-227)					
Fem-pop bypass	45	1 (4)	4 (6)	0.919	(0.799, 0.969)
Stent graft	45	0 (1)	1 (5)	0.980	(0.866, 0.997)
9 months (day 228-319)					
Fem-pop bypass	40	1 (5)	8 (14)	0.896	(0.768, 0.956)
Stent graft	44	0 (1)	2 (7)	0.980	(0.866, 0.997)
12 months (day 320-456)					
Fem-pop bypass	31	0 (5)	11 (25)	0.896	(0.768, 0.956)
Stent graft	42	0 (1)	11 (18)	0.980	(0.866, 0.997)

CI, Confidence interval.
Log-rank $P = .094$.
*Number in parenthesis represents cumulative events or censored observations through end of interval.

increased rate of hyperplasia at the proximal or distal ends of the graft may be due to overdilation with angioplasty and failure to cover the treatment area sufficiently with the covered stent.[8]

Most of the 13 thrombosed stent grafts (84%) were TASC C lesions. This finding is not surprising and supports the finding of others that the higher the TASC classification the lower the patency. Only one of our TASC D lesions treated thrombosed, but with only five in the group, definitive conclusions cannot reliably be drawn.

All patients treated by endovascular means required only outpatient care and in most instances were discharged on the same day, offering various cost savings in their care and earlier return to normal activities. This is supported by our length-of-stay analysis that shows a decrease of required hospital stay of nearly two thirds. The actual cost analysis was not performed in the current study, but follow-up analysis is planned. All but one of the patients in the endovascular group returned to work and normal daily activities ≤48 hours, and most were able to return ≤24 hours.

CONCLUSION

The choice of open surgical bypass vs percutaneously placed covered stents in the SFA has yet to be fully delineated. Nevertheless, our study shows no significant difference in synthetic bypass material placed in an open vs an endovascular fashion. We believe the results demonstrated in this study represent a significant step in defining endovascular treatment of disease in the SFA. The stent graft appears to be a viable option for primary SFA revascularization, particularly when vein is not available or if the patient is a poor candidate for conventional bypass. Correct graft sizing, avoiding overdilation, and not performing angioplasty beyond the area of planned stent coverage seem to be critically important technical facets of successful placement. We plan to continue to follow our cohort to assess longer-term outcomes.

AUTHOR CONTRIBUTIONS

Conception and design: DG, BT, WG
Analysis and interpretation: JK, SH, DG, CM, BT, WG
Data collection: JK, SH, DG, CM, BT, WG
Writing the article: JK, SH, DG
Critical revision of the article: JK, SH, DG, CM, BT, WG
Final approval of the article: JK, SH, DG, CM, BT, WG
Statistical analysis: CM
Obtained funding: DG
Overall responsibility: DG

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DISCUSSION

Dr Jon Matsumura (Chicago, Ill). Thirty-eight percent of the patients in the fem-pop group had Rutherford class 4 to 6 vs 18% in the endo group. Did you look at results stratified by CLI or do you have a multivariate analysis? Patency results may be influenced by the fem-pop group being enriched with patients with more severe ischemia.

If you did PTA and it looked beautiful, why did you still place a stent-graft? Did you consider having an arm with PTA and selective application of the device?

Dr John C. Kedora. We did not consider doing simply a PTA arm. We went into this study design with the thought that we would primarily treat patients with the stent graft, regardless of whether or not their PTA result was adequate. Our experience has shown this to give better long-term patency. As far as dividing into a subset of chronic limb ischemia categories, we did not stratify the data by that method.

Dr Enrico Ascher (Brooklyn, NY). Did you balloon angioplasty the lesion before placing the stent or did you place the stent graft and then balloon it?

Dr Kedora. All lesions were predilated by angioplasty and then the stent graft was placed. The stent graft was then modeled with angioplasty post deployment as well.

Dr Ascher. And how many of these were above the knee and how many were below the knee?

Dr Kedora. All these were placed above the knee.

Dr Takao Ohki (Bronx, NY). I wasn't quite sure about your inclusion criteria. But if I may recall, you said that the patient was enrolled if the lesion, based on the CTA or angiogram, appeared to be appropriate based on an attending's opinion. After all, you had a number of TASC Type A lesions, as well as B, C and D.

In the TASC document it does say clearly that TASC A is better treated with interventional treatment, whereas TASC D is best treated with bypass. The real question is what to do with TASC B and C. You should have randomized these patients, then it would have been a much more valuable study.

Dr Kedora. I think you are right that the evidence for TASC A lesions is that they are definitely better treated with endovascular means. I also believe, at least in our study, we wanted to do a true randomized, prospective study. All patients were well informed of the chance that if they had a less significant lesion that there was the chance that they would undergo a surgical bypass and, fortunately, we had patients that agreed to both.

Dr Kenneth Ouriel (Cleveland, Ohio). Sometimes when you do a study, you become an expert in a technique and you employ that technique in patients outside of the scope of the study. And so I have a somewhat politically charged question for you. What do you think about using these devices for popliteal aneurysms with the distal portion of the stent graft below the level of the knee joint?

Dr Kedora. Evaluation for treatment of popliteal aneurysms with this graft have yet to be done. In most cases, in our treatment group, there was disease in the proximal portion of the popliteal artery, and we were comfortable with placing the stent graft, at least in the proximal portion.

Dr Ouriel. Did you use these at all in patients that needed the distal to be below the level of the knee joint?

Dr Kedora. No, sir, we did not.